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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/096,593	06/12/98	O'CONNOR	A-64559-3/RT

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EXAMINER

COOK, L

ART UNIT

PAPER NUMBER

1641

14

DATE MAILED: 10/03/00

Pl ase find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/096,593

Applicant(s)

O'CONNOR et al.

Examiner

Lisa V. Cook

Group Art Unit
1641



☒ Responsive to communication(s) filed on May 22, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 18-28 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 18-28 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☒ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

1. Applicants' response to the Office Action mailed November 22, 1999 (Paper #12 filed 5/22/00) is acknowledged. Currently, claims 18-28 are pending and under consideration. In response to the supplemental amendment-B filed in 5/22/00 in Paper#12, claims 18-28 are reflective on this entry. Claims 18-28 were rejected under 35 U.S.C.112, second paragraph. Claims 18-28 were rejected under 35 U.S.C. 103(a).

REMARKS

Information Disclosure Statement

2. Applicants' supplemental IDS (Information Disclosure Statement) on PTO 1449, filed on May 22, 2000 was considered by the examiner.

OBJECTIONS WITHDRAWN

Specification

3. The noted objections to the specification in paper #8, because of the following informalities:

- I. On page 16, System 7 at the top of the page is not identified.
Please label as system 7 or accordingly.
- II. In Line 31, page 35 there appears to be something missing after the phrase "not limited to".

Have been properly addressed, thus the objection is withdrawn.

OBJECTIONS MAINTAINED

Drawings

4. Applicants have deferred the corrective action, eliminating defects in the drawings cited by the Draftsperson under 37 CFR 1.84 or 1.152 on PTO-948. However, formal correction of the noted defect can be deferred until the application is allowed by the examiner.

REJECTIONS WITHDRAWN

Claim Rejections - 35 USC § 112

5. Claims 18-28 stand withdrawn from rejection under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record on paper number 8.

B. In claims 18 and 20, the use of "self-assembled monolayer" has been clearly defined and supported by prior art teachings.

Claim Rejections

6. With respect to the claim rejections under 35 U.S.C. 103 for reasons of record in paper #8, Applicant argues that the references do not anticipate the instant invention because the cited prior art, alone or in combination does not disclose each of the claimed elements. Specifically, the combinations do not disclose the use of self-assembled monolayers, covalently attached conductive oligomer spacers, or the use of faradaic impedance to detect the binding of an analyte. This argument was fully considered and found persuasive.

7. The following rejections are withdrawn:

I. Claims 18-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vreeke et al (U.S.Patent#5,534,132) and O'Daly et al. (U.S.Patent#5,391,272) in view of Kossovsky et al. (U.S.Patent#5,585,646).

II. Claims 18-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al (U.S.Patent#5,972,199) and Skotheim et al. (U.S.Patent#5,089,112) in view of Kossovsky et al. (U.S.Patent#5,585,646).

III. Claims 18-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delamarche et al. (American Chemical Society, Languir 1996, Vol.12, pages 1997-2006) in view of Kossovsky et al. (U.S.Patent#5,585,646) and in further view of Gafni et al. (Chem. Eur. J. 1996, Vol.2, No.7).

REJECTIONS MAINTAINED

Claim Objections

8. Claim 19 is objected to under 37 CFR 1.75(c) as being in improper form because it is a multiple dependent claim dependent on subsequent claim 20. See MPEP § 608.01(n). Accordingly, claim 19 has not been further treated on the merits.

Claim Rejections - 35 USC § 112

9. Claims 19-28 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record on paper number 8.

A. Claim 19 is indefinite because it is unclear as to what is encompassed within the phrase "processor". Although applicant points to the disclosure to define this term, (page 50 – lines 13-15) this passage only defines the design of the processor as it relates to the electrode configuration of the instant invention. The actual processor function as to its limitations is not clearly defined. Is it applicants intend to claim any system which can receive an output signal? Please explain.

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B. Claim 22 is vague and indefinite in the use of the conductive oligomer formula. The intended composition of B has not been outlined. Further, D is not defined when g is 1. Applicant argues that the intended compositions are defined by the specification page 22, lines 4-21. However, the claims do not include the specifics of the disclosure.

Further, the word "preferably" is unclear in this context. It is unclear whether this word is meant to impart some greater scope because certain embodiments are preferred, perhaps due to some greater scope of enablement. If this is not the case it is suggested that this word be deleted. Clarification is requested.

NEW GROUNDS OF REJECTION

Information Disclosure Statement

10. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 or applicant on PTO-1449 has cited the references they have not been considered.

Specification

11. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

12. The use of several trademarks is noted in this application. They should be capitalized wherever they appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks. (For example, see page 26 – Teflon®).

13. The disclosure contains several drawing on pages 14-20 and 22-33 it is noted that the drawing should be submitted to the office as required by 37 CFR 1.81.

Double Patenting

14. Double patenting obviousness-type rejection:

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 18-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 6,096,273. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions are drawn to electrodes having

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monolayers and conductive oligomers for analyte detection. The instant claims are directed to non-nucleic acid analytes while the patent of Kayyem et al. is directed to nucleic acid analytes. However, it would have been obvious to the skilled practitioner in the art to employ other analyte binding entities (any ligand binding pair) in the coated apparatus to detect other unknown compositions because differences in the type of electron donor/acceptor moieties, electron transfer mediators and in the configuration, would have been known to one of ordinary skill in the art to be variable and discretionary.

15. Provisional double patenting rejection: obviousness-type

Claims 18-28 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-40 of copending Application No. 08/873,597. Although the conflicting claims are not identical, they are not patentably distinct from each other because both patent applications are drawn to an apparatus comprising electrodes with conductive oligomer and monolayers. The differences are in the analyte being detected. The instant invention detects non nucleic acid targets, wherein copending application no. 08/873,597 detects nucleic acids. This difference in the presence or configuration of the combination of a nucleic acid probe or another target sequence with the instant invention would have been known to one of ordinary skill in the art to be variable and discretionary based on experimental design and desired results.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claims 18-22 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 08/873,597 and U.S. Patent # 6,096,273 which have a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future patenting of the conflicting application.

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131. For applications filed on or after November 29, 1999, this rejection might also be overcome

by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

I. Claims 18,19, 21 and 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keen (U.S.Patent #6,060,327) in view of Kossovsky et al. (U.S.Patent#5,585,646).

Keen discloses sensors to detect an analyte without mediators. The sensors have a plurality of conductive polymer strands attached to a plurality of molecular recognition head groups (having affinity for an analyte) which are attached to an electrode substrate. The conductive polymer strands maybe multi-stranded nucleic acids, electron transport proteins, synthetic organic and inorganic conducting polymers, metal crystallite molecular wires, and Langmuir-Blodgett conducting films. (see column 7, lines 44-63).

Keen (U.S.Patent #6,060,327) differs from the instant invention in failing to specifically teach self-assembled monolayers in their device designs.

However, Kossovsky et al. disclose improved bioelectronics devices in comprising a layer of a polyhydroxy oligomer that is spaced between the surface of a semiconductive material (applicants monolayer) and a electronically active biochemical molecule (applicants binding ligand) which is bound to the semiconductive surface of an electronic device (applicants electrode). The layer of polyhydroxy oligomer functions as a biochemical stabilization layer to prevent denaturization of the electronically active

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biochemical molecule (Abstract). The stabilization layer is made up of one or more polyhydroxy oligomers. Exemplary polyhydroxy oligomers include carbohydrates, carbohydrate derivatives, and other macro molecules with carbohydrate like components.

Kossovsky et al. further teach that the surface modification concept and the electron donor-acceptor concept can be combined at the semiconductor surface and utilized in various methods. Specifically cited is the method of Colvin et al. (Column 4, Lines 12-25). Colvin et al. Construct devices by attaching semiconductor nanocrystals to metal surfaces using self assembled monolayers as bridging compounds.

Keen (U.S. Patent #6,060,327) and Kossovsky et al. (U.S. Patent #5,585,646) are analogous art because they are from the same field of endeavor, both inventions teach the fabrication of electrochemical biosensors.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the self assembled monolayers taught by Kossovsky et al. in the method of Keen to perform analyte detection in an affinity assay system because such self assembled monolayers as taught by Kossovsky et al. are well known in the art. A person of ordinary skill in the art would have had a reasonable expectation of success utilizing such materials, because Kossovsky et al. disclosed that the use of self assembled monolayers allows the molecules to be held in a specific orientation with respect to the metal and are applicable in many system designs (Column 4, Lines 12-25).

recent advances have extended self assembled monolayers beyond the prototype gold/thiol systems. Fatty acids on aluminum, silanes on silicon, isonitriles on platinum and rigid phosphates on metals are all examples.

Kossofsky et al. also teach the use of the any denaturization of the biochemical material which might be caused by the semiconductor material is eliminated or substantially reduced by placing the stabilization layer of polyhydroxy oligomers between the biochemical material and the semiconductor (Column 7, Lines 13-18).

II. Claims 20-21 and 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keen (U.S. Patent #6,060,327) in view of Wohlstadter et al. (U.S. Patent #6,090,545).

Please see previous discussion of Keen (U.S. Patent #6,060,327) as set forth above.

Keen differs from the instant invention in not teaching an array of first measuring electrodes. (claim 20).

Wohlstadter et al. disclose patterned, multi-array multi-specific surfaces on a support (PMAMS) that are electronically excited in electrochemiluminescence based tests. The PMAMS can be generated from self- assembled monolayers on a surface. (column 13, lines 10-31).

Keen (U.S. Patent #6,060,327) and Wohlstadter et al. (U.S. Patent #6,090,545) are analogous art because they are from the same field of endeavor, both inventions teach analyte detection sensors.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to multi-electrode arrays as taught by Wohlstadter et al. in the method of Keen to perform analyte detection in an affinity assay system because such multi-electrode arrays as taught by Wohlstadter et al. are well known in the art. A person of ordinary skill in the art would have had a reasonable expectation of success utilizing at least two measuring electrodes, because Wohlstadter et al. disclosed that the use of multi-electrode arrays allows for the simultaneous assay of a plurality of analytes in a single sample. (Column 3, lines 36-39).

One of ordinary skill would have been motivated to do this because Wohlstadter et al. taught that their invention reduced the time and cost associated with individual analyte assays. (column 3, lines 33-35).

III. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keen (U.S. Patent #6,060,327) in view of Kossovsky et al. (U.S. Patent #5,585,646) as applied to claims 18, 19, 21, and 24-28 above, and further in view of Meade (U.S. Patent #6,013,459).

See previous discussion of Keen (U.S. Patent #6,060,327) in view of Kossovsky et al. (U.S. Patent #5,585,646).

Keen and Kossovsky et al. differ from the instant invention in not specifically teaching the conductive oligomer formulas exemplified in claims 22 and 23.

However, Meade teaches methods of detecting analytes utilizing electron transfer. The invention involves an electrode covalently attached to a redox active complex. The complex includes a binding ligand. The particular apparatus for detection has a test chamber comprising a first measuring electrode, a second measuring electrode an AC/DC voltage source electrically connected to the test chamber, and an optical signal processor for detection. (column 2, lines 4-20). In one embodiment the redox active complex is attached to an electrode via a conductive oligomers that are the same oligomers structures of the instant invention, specifically claims 22 and 23. (see column 8 and column 12).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the oligomers structures as taught by Meade in the method of Keen (U.S. Patent #6,060,327) in view of Kossovsky et al. (U.S. Patent #5,585,646) to perform analyte detection in an affinity assay system because such oligomers as taught by Meade are well known in the art. A person of ordinary skill in the art would have had a reasonable expectation of success utilizing these structures, because Meade disclosed that these structures were suitable for sensory embodiments and analyte detection. (i.e. column 7, lines 16-45).

One of ordinary skill would have been motivated to do this because Meade taught that their inventive oligomers resulted in high conductivity, exhibited sufficient

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solubility in organic solvents and/or water, and were chemically resistant to assay reactions. (column 8, lines 1-7).

IV. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keen (U.S. Patent #6,060,327) in view of Wohlstadter et al. (U.S. Patent #6,090,545) as applied to claims 20-21 and 24-28 above, and further in view of Meade (U.S. Patent #6,013,459).

See previous discussion of Keen (U.S. Patent #6,060,327) in view of Wohlstadter et al. (U.S. Patent #6,090,545).

Keen (U.S. Patent #6,060,327) and Wohlstadter et al. (U.S. Patent #6,090,545) differ from the instant invention in not specifically teaching the conductive oligomer formulas exemplified in claims 22 and 23.

However, Meade teaches methods of detecting analytes utilizing electron transfer. The invention involves an electrode covalently attached to a redox active complex. The complex includes a binding ligand. The particular apparatus for detection has a test chamber comprising a first measuring electrode, a second measuring electrode an AC/DC voltage source electrically connected to the test chamber, and an optical signal processor for detection. (column 2, lines 4-20). In one embodiment the redox active complex is attached to an electrode via a conductive oligomers that are the same oligomers structures of the instant invention, specifically claims 22 and 23. (see column 8 and column 12).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the oligomers structures as taught by Meade in the method of Keen (U.S. Patent #6,060,327) in view of Wohlstadter et al. (U.S. Patent #6,090,545) to perform analyte detection in an affinity assay system because such oligomers as taught by Meade are well known in the art. A person of ordinary skill in the art would have had a reasonable expectation of success utilizing these structures, because Meade disclosed that these structures were suitable for sensory embodiments and analyte detection. (i.e. column 7, lines 16-45).

One of ordinary skill would have been motivated to do this because Meade taught that their inventive oligomers resulted in high conductivity, exhibited sufficient solubility in organic solvents and/or water, and were chemically resistant to assay reactions. (column 8, lines 1-7).

18. For reasons aforementioned, no claims are allowed.


19. Examiner apologies for any inconvenience the new rejections have imposed on Applicant. Accordingly, **THIS ACTION IS MADE NON-FINAL.**

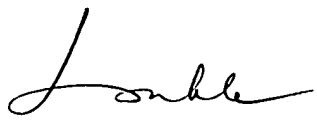
20. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 308-4242, which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (703) 305-0808. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Lisa V. Cook
Patent Examiner
Art Unit: 1641
CM1 7D16


LONG V. LE
SUPERVISORY PATENT EXAMINER
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